

117TH CONGRESS  
2D SESSION

# H. R. 8299

To allow for devices with a predetermined change control plan to be marketed without submitting a supplemental application or premarket notification if the changes to such devices are consistent with such plan.

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## IN THE HOUSE OF REPRESENTATIVES

JULY 7, 2022

Mr. BILIRAKIS (for himself and Mr. O'HALLERAN) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To allow for devices with a predetermined change control plan to be marketed without submitting a supplemental application or premarket notification if the changes to such devices are consistent with such plan.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. PREDETERMINED CHANGE CONTROL PLANS**

4                   **FOR DEVICES.**

5       (a) IN GENERAL.—Chapter V of the Federal Food,  
6 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-  
7 ed by inserting after section 515B (21 U.S.C. 360e-3) the  
8 following:

1   **“SEC. 515C. PREDETERMINED CHANGE CONTROL PLANS**

2                   **FOR DEVICES.**

3       **“(a) APPROVED DEVICES.—**

4               **“(1) IN GENERAL.—**Notwithstanding section  
5       515(d)(5)(A), a supplemental application shall not  
6       be required for a change to a device approved under  
7       section 515, if such change is consistent with a pre-  
8       determined change control plan that is approved  
9       pursuant to paragraph (2).

10       **“(2) PREDETERMINED CHANGE CONTROL**  
11       **PLAN.—**The Secretary may approve a predetermined  
12       change control plan submitted in an application, in-  
13       cluding a supplemental application, under section  
14       515 that describes planned changes that may be  
15       made to the device (and that would otherwise re-  
16       quire a supplemental application under section 515),  
17       if the device remains safe and effective without any  
18       change.

19       **“(3) SCOPE.—**The Secretary may require that a  
20       change control plan include labeling required for  
21       safe and effective use of the device as such device  
22       changes pursuant to such plan, notification require-  
23       ments if the device does not function as intended  
24       pursuant to such plan, and performance require-  
25       ments for changes made under the plan.

26       **“(b) CLEARED DEVICES.—**

1           “(1) IN GENERAL.—Notwithstanding section  
2        510(k), a premarket notification shall not be re-  
3        quired for a change to a device cleared under section  
4        510(k), if such change is consistent with an estab-  
5        lished predetermined change control plan granted  
6        pursuant to paragraph (2).

7           “(2) PREDETERMINED CHANGE CONTROL  
8        PLAN.—The Secretary may clear a predetermined  
9        change control plan submitted in a notification sub-  
10       mitted under section 510(k) that describes planned  
11       changes that may be made to the device (and that  
12       would otherwise require a new notification), if—

13           “(A) the device remains safe and effective  
14        without any such change; and

15           “(B) the device would remain substantially  
16        equivalent to the predicate.

17           “(3) SCOPE.—The Secretary may require that a  
18        change control plan include labeling required for  
19        safe and effective use of the device as such device  
20        changes pursuant to such plan, notification require-  
21       ments if the device does not function as intended  
22        pursuant to such plan, and performance require-  
23       ments for changes made under the plan.

24           “(c) PREDICATE DEVICES.—In making a determina-  
25        tion of substantial equivalence pursuant to section 513(i),

1 the Secretary shall not compare a device to changed  
2 versions of a device implemented in accordance with an  
3 established predetermined change control plan as a predi-  
4 cate device. Only the version of the device cleared or ap-  
5 proved, prior to changes made under the predetermined  
6 change control plan, may be used by a sponsor as a predi-  
7 cate device.”.

8 (b) CONFORMING AMENDMENTS.—

9 (1) CLEARED DEVICES.—Section 510(l)(1) of  
10 the Federal Food, Drug, and Cosmetic Act (21  
11 U.S.C. 360(l)(1)) is amended, in the first sentence,  
12 by inserting “, or with respect to a change that is  
13 consistent with a predetermined change control plan  
14 cleared under section 515C” before the period at the  
15 end.

16 (2) APPROVED DEVICES.—Section  
17 515(d)(5)(A)(i) of the Federal Food, Drug, and Cos-  
18 metic Act (21 U.S.C. 360e(d)(5)(A)(i)) is amended  
19 by striking “A supplemental” and inserting “Unless  
20 the change is consistent with a predetermined  
21 change control plan approved under section 515C, a  
22 supplemental”.

23 (3) DOCUMENTATION OF RATIONALE FOR SIG-  
24 NIFICANT DECISIONS.—Section 517A(a)(1) of the

1       Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
2       360g-1(a)(1)) is amended to read as follows:

3                 “(1) IN GENERAL.—The Secretary shall provide  
4       a substantive summary of the scientific and regu-  
5       latory rationale for any significant decision of the  
6       Center for Devices and Radiological Health regard-  
7       ing submission or review of a report under section  
8       510(k), a petition for classification under section  
9       513(f), an application under section 515, or an ap-  
10      plication for an exemption under section 520(g), in-  
11      cluding documentation of significant controversies or  
12      differences of opinion and the resolution of such con-  
13      troversies or differences of opinion.”.

